

The opinion in support of the decision being entered  
today is not binding precedent of the Board

Filed by: Trial Section Merits Panel  
Mail Stop Interferences  
P.O. Box 1450  
Alexandria, VA 22313-1450  
Tel: 703-308-9797  
Fax: 703-305-0942

Paper No. **14**

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

OSIRIS THERAPEUTICS, INC  
Junior Party,  
(Patent 6,030,836),

v.

CASE WESTERN RESERVE UNIVERSITY  
Senior Party,  
(Application 09/321,655).

Patent Interference No. 105,197

Before LANE, MEDLEY, and TIERNEY Administrative Patent Judges.

MEDLEY, Administrative Patent Judge.

**FAXED**

**APR 22 2004**

**PAT. & T.M. OFFICE  
BOARD OF PATENT APPEALS  
AND INTERFERENCES**

**DECISION ON PRELIMINARY MOTION**

**A. Introduction**

This interference was declared on 9 January 2004. Osiris Therapeutics, Inc. (Osiris) disclaimed its claim 18 (Paper 20), and filed, along with Case Western Reserve University (Case Western) a joint preliminary motion 1 for no interference-in-fact between the remaining Osiris and Case Western claims (Paper 19).

## **B. Findings of fact**

The record supports the following findings, and any additional findings made throughout the opinion, by at least a preponderance of the evidence.

1. Osiris is involved on the basis of patent 6,030,836, issued 29 February 2000, based on application 09/327,840, filed 8 June 1999.

2. Case Western is involved on the basis of application 09/321,655, filed 28 May 1999.

3. Case Western has been accorded benefit for the purpose of priority of application 60/087,284, filed 29 May 1998.

4. Count 1 is Claim 18 of Osiris.

5. Osiris claim 18 depends on claim 1. Osiris claim 1 and claim 18 are as follows:

1. A method of maintaining human hematopoietic stem cells in vitro comprising co-culturing human mesenchymal stem cells with the hematopoietic stem cells such that at least some of the hematopoietic stem cells maintain their stem cell phenotype.

18. The method of claim 1 wherein said hematopoietic stem cells are genetically modified.

6. The claims of the parties are:

Osiris: 1-25

Case Western: 2-5

7. The following claims were originally designated as corresponding to Count 1:

Osiris: 1-3, 8, 12, 13, and 18

Case Western: 2-5

8. The following claims were originally designated as not corresponding to count:

Osiris: 4-7, 9-11, 14-17, and 19-25

Case Western: None

9. Osiris filed a paper disclaiming its claim 18 (Paper 20).

10. The parties filed a joint preliminary motion for no interference in fact between Osiris' remaining claims 1-3, 8, 12 and 13 and Case Western's claims 2-5 (Paper 19).

11. The remaining Osiris claims designated as corresponding to the count 1 are as follows:

1. A method of maintaining human hematopoietic stem cells in vitro comprising co-culturing human mesenchymal stem cells with the hematopoietic stem cells such that at least some of the hematopoietic stem cells maintain their stem cell phenotype.
2. The method of claim 1 wherein the hematopoietic stem cells are CD34+ cells.
3. The method of claim 1 wherein the mesenchymal stem cell population is allogeneic or autologous to the hematopoietic stem cell population.
8. A composition for maintaining human hematopoietic stem cells in vitro such that at least some of the hematopoietic stem cells retain their stem cell phenotype comprising human hematopoietic stem cells and human mesenchymal stem cells.
12. The method of claim 3 wherein the mesenchymal stem cell population is allogeneic to the hematopoietic stem cell population.
13. The method of claim 3 wherein the mesenchymal stem cell population is autologous to the hematopoietic stem cell population.
12. The Case Western claims 2-5 originally designated as corresponding to the count are

as follows:

2. The method of Claim 5 wherein the mesenchymal stem cells are autologous to the hematopoietic progenitor cells.

3. The method of Claim 5 wherein the mesenchymal stem cells are allogeneic to the hematopoietic progenitor cells.
4. The method of Claim 5 further comprising harvesting the transduced human progenitor cells from the mesenchymal stem cells.
5. A method for transforming hematopoietic progenitor cells to express a protein, comprising co-culturing human hematopoietic progenitor cells with isolated human mesenchymal stem cells, and transforming the human hematopoietic progenitor cells with a polynucleotide comprising exogenous genetic material encoding a protein in the presence of the isolated human mesenchymal stem cells, wherein said protein is expressed.

### **C. Discussion**

At the time the interference was declared, the count was Osiris patent claim 18. Osiris claim 18 depends from Osiris claim 1, and recites that the hematopoietic stem cells of claim 1 are genetically modified. It was determined that Osiris claim 18 defined the same patentable invention as at least Case Western's claim 5, and therefore an interference was declared (Paper 1). After the interference was declared, Osiris disclaimed its claim 18 (Paper 20). In effect, Osiris has disclaimed the count. However, such disclaimer is not treated as a request for entry of adverse judgment against Osiris, since Osiris has not disclaimed all of the claims that were originally designated as corresponding to the count. 37 CFR § 1.662(c).

It is in that light that Osiris and Case Western jointly move under 37 CFR § 1.633(b) for no interference-in-fact between any one of Osiris' remaining claims 1-3, 8, 12, and 13 and any one of Case Western's claims 2-5 that were originally designated as corresponding to the count. Although the motion is uncontested, the parties bear the burden to demonstrate that they are entitled to the relief sought. 37 CFR § 1.637(a). See GN v. SW, 57 USPQ2d 1073 (BPAI 2000).

The test for no interference-in-fact is a one way nonobviousness test. See, Eli Lilly v. Board of Regent of the Univ. of Wash., 334 F.3d 1264, 67 USPQ2d 1161 (Fed. Cir. 2003). The parties need demonstrate that (1) no one of Osiris' claims 1-3, 8, 12 and 13 anticipates or renders obvious any one of Case Western's claims 2-5 or (2) no one of Case Western's claims 2-5 anticipates or renders obvious any one of Osiris's claims 1-3, 8, 12 and 13.

Osiris and Case Western seek to demonstrate that no one of Osiris' claim 1-3, 8, 12 and 13 anticipates or renders obvious any one of Case Western's claims 2-5 and that no one of Case Western's claims 2-5 anticipates or renders obvious any one of Osiris' claims 1-3, 8, 12 and 13 (Paper 19 at 6-7). As discussed above, only a one way analysis is necessary to demonstrate that there is no interference-in-fact. For purposes of our discussion, we focus our attention on the parties' representation that no one of Osiris' claims 1-3, 8, 12 and 13 anticipates or renders obvious any one of Case Western's claims 2-5.

The joint preliminary motion 1 sets forth the differences between Osiris' claims 1-3, 8, 12 and 13 and Case Western's claims 2-5 and sufficiently demonstrates that no one of Osiris' claims 1-3, 8, 12 and 13 directed to maintaining the phenotype of hematopoietic stem cells by co-culturing the hematopoietic stem cells with mesenchymal stem cells anticipates any one of Case Western's claims 2-5 directed to transforming hematopoietic progenitor cells with exogenous genetic material in the presence of an isolated human mesenchymal stem cell.

The joint preliminary motion 1 also sets forth and discusses (1) the differences between Osiris claims 1-3, 8, 12 and 13 and Case Western's claims 2-5, (2) the prior art known by the parties, and (3) why no one of Osiris' claims 1-3, 8, 12 and 13, in view of the relevant cited prior art, would render obvious any one of Case Western's claims 2-5 (Paper 19 at 11-13).

Specifically, as explained by the parties, it was not known at the time of the Case Western invention that human mesenchymal stem cells could be used to enhance the transduction of human hematopoietic progenitor cells for the expression of exogenous gene products (Paper 19 at 11).


The parties, through their preliminary motion 1, sufficiently discuss and explain why, given any one of the Osiris claims 1-3, 8, 12 and 13 as prior art, a method of transducing human hematopoietic progenitor cells in the presence of isolated human mesenchymal stem cells as recited in the Case Western claims 2-5 would not have been obvious in light of the prior art known at the time of the Case Western invention.


We accept the statement on page 14 of the motion that “there is nothing in the prior art which discloses or suggests to one of ordinary skill in the art that one can transform hematopoietic progenitor cells to express a protein by culturing hematopoietic progenitor cells in the presence of isolated mesenchymal stem cells” as a representation by Osiris, Case Western and the inventors of the Osiris patent and Case Western application that they are unaware of any prior art that would render the Case Western claims obvious, given the Osiris claims as prior art. On that basis, and based on the analysis and discussion presented in the joint preliminary motion 1, the joint preliminary motion 1 is granted.

Since there is no interference-in-fact between any one of Case Western’s claims 2-5 and any one of Osiris’ remaining claims 1-3, 8, 12 and 13, the interference is terminated in a separate, concurring paper.

**ORDERED** that the “PARTY OSIRIS THERAPEUTICS, INC. AND CASE WESTERN

**FURTHER ORDERED** that a copy of the Osiris Therapeutics Inc. disclaimer of its claim 18 of U.S. patent 6,030,836 (Paper 19) shall be made of record in files of application 09/321,655 and U.S. Patent 6,030,836; and

  
SALLY GARDNER LANE  
Administrative Patent Judge

  
SALLY C. MEDLEY  
Administrative Patent Judge

  
MICHAEL P. TIERNEY  
Administrative Patent Judge

cc (via facsimile):

Counsel for Osiris:

Elliot M. Olstein, Esq.  
CARELLA, BYRNE, BAIN, GILFILLAN,  
CECCHI, STEWART & OLSTEIN  
5 Becker Farm Road  
Roseland, N.J. 07068

Fax: 973-994-1744

Counsel for CWRU:

Richard S. Wesorick, Esq.  
TAROLLI, SUNDHEIM, COVELL & TUMMINO LLP  
526 Superior Avenue, Suite 1111  
Cleveland, OH 44114-1400

Fax: 216-621-4072